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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/560,544 | 12/14/2005 | Breda Mary Cullen | 101713-5033 | 6443 |

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| EXAMINER |
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WESTERBERG, NISSA M

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| ART UNIT | PAPER NUMBER |
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1618

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05/20/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,544

Applicant(s)

CULLEN ET AL.

Examiner

NISSA WESTERBERG

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-13 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-13 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments, filed April 5, 2011, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 5, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0368253) in view of Britton et al. (US 2003/0007957) and/or Cullen et al. (Intl J Biochem Cell Bio, 2002). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 5, 2010 and those set forth below.

Applicant traverses this rejection on the grounds that the assertion that Britton teaches chitosan and oxidized regenerated cellulose (ORC) as functional equivalents is overly broad and not supported by the facts. Britton at most teaches that chitosan and ORC are equivalent for the narrow purpose taught by Britton of providing a gelatinous, semi-liquid to semi-solid when mixed with unactivated platelet-rich plasma and provides no suggestion or motivation to functionally equate chitosan with ORC. Under acidic condition, the chitosan used by Partain is protonated and thus able to bind to negatively charged surfaces such as mucosal membranes. This is very different from ORC which will only form an anionic moiety.

This argument is unpersuasive. The primary reference of Partain not only teaches solid forms but also that solutions can be prepared (e.g., col 12, ln 34). The person of ordinary skill in the art would have a reasonable expectation of success that

the materials used in Britton could also be prepared as a solid support like the medicated sheets or bandages or patches. Regarding the charge of the particular polymer, Britton teaches that polymers of either charge can be used and applied directly to a wound or surgery incision and thus the materials are compatible with a wound site. Applicants arguments also do not discuss the teaching of Cullen (discussed in full on p 8 of the previous office action), which teaches the advantageous properties provided by ORC in chronic wound repair, motivating inclusion of this material in the solid drug delivery preparations of Partain such as the medicated bandages or patches.

Applicant also argues that Britton provides no suggestion or discussion of the use of a material that is bioabsorbable and does not teach or suggest the preparation of a bioabsorbable substrate.

This argument is unpersuasive. The properties the substrate are determined by the materials which are used to prepare the substrate. The instant claims indicate that a substrate comprising oxidized cellulose is a solid bioabsorbable substrate. That Britton does not use the term 'bioabsorbable' to describe oxidized cellulose is insufficient to overcome the rejection as the same materials must have the same properties.

6. Claims 1, 5 – 7, 11, 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Britton et al., Cullen et al. as applied to claims 1, 5, and 20 above, and further in view of Shanbrom (US 6,361,786). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 5, 2010 and those set forth herein.

Applicant has not specifically addressed this rejection other than referring to Shanbrom, so the rejection is maintained for the reasons set forth above with regard to Partain, Britton and/or Cullen set forth above.

7. Claims 1, 5 – 11, 13 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Britton et al., Cullen et al. and Shanbrom as applied to claims 1, 5 – 7, 11, 13 and 20 above, and further in view of Nimrod et al. (WO 87/05517). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 5, 2010 and those set forth herein.

Applicant has not specifically addressed this rejection other than referring to Nimrod, so the rejection is maintained for the reasons set forth above with regard to Partain, Britton and/or Cullen set forth above.

8. Claims 1, 5 – 7, 11 - 13 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Britton et al., Cullen et al. and Shanbrom as applied to claims 1, 5 – 7, 11, 13 and 20 above, and further in view of Gibbins (US 6,255,858). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 5, 2010 and those set forth herein.

Applicant has not specifically addressed this rejection other than referring to Gibbins, so the rejection is maintained for the reasons set forth above with regard to Partain, Britton and/or Cullen set forth above.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 – 3 and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 9 and 11 of U.S. Patent No. 7,833,790 in view of Partain et al. (EP 0368253). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 5, 2010 and those set forth herein. Since the mailing of the last Office Action, Application 11/608553 has issued as U.S. Patent 7, 833,790, causing this rejection to be converted from a provisional to a non-provisional, nonstatutory obviousness-type double patenting rejection.

Applicants traverse this rejection on the grounds set forth above regarding the inapplicability of Partain.

This argument is unpersuasive. In the double patenting rejection, Partain is cited for its teaching of the inclusion of an antioxidant dyestuff to the wound dressing compositions claimed in '553. The Examiner believes that Applicant is referring to the arguments above regarding the different charges of the ORC and the chitosan materials of Partain but nothing in those arguments argues why the person of ordinary skill in the art would only look at wound dressing materials having the same charge when looking to see what additive(s) can be included in the composition. Nothing in Partain, applicant's arguments or the knowledge of the person having ordinary skill in the art

would indicate that a change in the charge of the polymer would render the composition unsuitable for delivery of acridine dyes to a wound. If this argument is not what Applicant was referring to, the next response should contain more specific arguments.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NISSA WESTERBERG whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nissa M Westerberg/
Primary Examiner, Art Unit 1618